IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
ETHICON WAVE 4 CASES LISTED IN EXHIBIT A	JUDGE GOODWIN

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF JOHN R. WAGNER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") submit this response in opposition to Plaintiffs' motion to exclude general opinions of John R. Wagner, M.D. (Doc. 3617).

INTRODUCTION

Dr. Wagner has practiced urogynecology for approximately 30 years. Ex. A hereto, Curriculum Vitae at 1. In addition to being double board certified in Female Pelvic Medicine and Reconstructive Surgery and Obstetrics and Gynecology, he is certified by the American Association of Gynecologic Laparascopy and is an accredited member of the American Institute of Minimally Invasive Surgery. *Id.* A former Chief Resident, Dr. Wagner is a Fellow of the American College of Obstetrics and Gynecology. *Id.* A former preceptor for TVT courses, for several years he has taught pelvic surgery to residents in New York and has served as a Clinical Associate Professor for the Hofstra University School of Medicine. *Id.* at 2-4; Ex. B to Pl's motion, Expert Report at 1-3; Ex. B hereto. Dr. Wagner has published several articles in peer-reviewed publications, and he has been asked to lecture about urogynecology topics throughout the country on many occasions. Ex. A hereto, Curriculum Vitae at 2.

Dr. Wagner has performed numerous stress urinary incontinence ("SUI") surgeries throughout his career using a number of products and techniques, such as Kelly plications, Burch colposuspension, needle suspension procedures, autologous slings, and synthetic midurethral slings. Ex. B to Pl's motion, Expert Report at 1-2; Ex. B hereto, 3/13/17 Dep. 43:8-44:12. He has implanted over 2000 of Ethicon's devices for the surgical treatment of SUI, including approximately 600 to 800 TVT devices, and he has also explanted a number of pelvic mesh devices. *Id.* at 95:15-24, 120:11-23, 133:14-21; Ex. B to Pl's motion, Expert Report at 4, 36.

In this wave of cases, Dr. Wagner intends to offer opinions generally addressing the utility and safety of Ethicon's TVT device. His opinions are based upon his education, medical training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other materials. Ex. B to Pl's motion, Expert Report; Ex. C hereto, Reliance List. In their motion, Plaintiffs have made vague challenges to certain aspects of Dr. Wagner's opinions. Plaintiffs' challenges are not tied to the opinions actually offered by Dr. Wagner in his report, but instead, are generic and regurgitated from Plaintiffs' challenges of Ethicon's other experts. Dr. Wagner is well-qualified to offer the opinions set forth in his report, her opinions are supported by a reliable methodology, and Plaintiffs' challenges lack merit.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. The Court should allow Dr. Wagner to offer opinions about warnings.

Without citing a single statement set forth in Dr. Wagner's expert report, Plaintiffs make a generic challenge to Dr. Wagner's ability to testify about warnings. In his report, Dr. Wagner

opines that Ethicon's instructions for use ("IFUs") adequately and accurately warned surgeons of risks, *taking into account risks that were commonly known*, and therefore, were not required to be included in the IFUs. Ex. B to Pl's motion, Expert Report at 47-51. Dr. Wagner's opinions are consistent with the applicable legal standard, which imposes a duty to warn only of hidden medical risks not commonly known to pelvic floor surgeons. He is qualified to testify as to common knowledge among pelvic floor surgeons, whether or not certain medical risks exist, and the role that IFU package inserts play in the decision-making of a pelvic floor surgeon, all of which relate to this standard.

Dr. Wagner also explained that certain alleged risks, such as cytotoxicity and degradation, did not need to be included in the IFUs because the medical literature and his experience has led him to conclude that those alleged risks do not cause any clinical consequences. *Id.* at 49-50. He will also testify that IFUs are intended merely to "introduce somebody to a product" and that surgeons should rely on other sources, including medical literature, before implanting a TVT device. Ex. B hereto, 3/13/17 Dep. 89:4-21, 107:6-15, 109:1-8.

Dr. Wagner, who uses the IFUs to teach his residents, has based his warnings opinions on many sources, including his training and clinical experience, his extensive review of medical literature, his review of the FDA's "Blue Book Memo," his review of the IFUs, and his review of the TVT Surgeon's Resource Monograph. *Id.* at 87:1-5, 187:23-189:12; Ex. B to Pl's motion, Expert Report at 47-50. These are ample bases for his opinions on common knowledge, the existence of medical risk, and role of the IFU in surgical practice, which justifies reliance on common knowledge.

Plaintiffs claim that Dr. Wagner is not competent to testify about these issues because he does not have experience designing an IFU. Ethicon concedes that Dr. Wagner is not a regulatory expert and will not opine on warnings from that perspective. Dr. Wagner, however, will opine on these subjects, which bear on the completeness and accuracy of the IFU warnings from a clinical perspective, based on his knowledge of and clinical experience with these devices as well as his review of the literature. Plaintiffs do not challenge Dr. Wagner's clinical expertise or the sufficiency of his review of the literature.[1]

Consistent with the Court's prior rulings, Dr. Wagner, as a urogynecologist, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582231, at *3 (S.D.W. Va. Sept. 1, 2016). Indeed, Dr. Wagner's report and deposition testimony detail his extensive experience with these devices, including particular risks and complications he has experienced and researched, and his report explains his opinions in detail. *E.g.*, Ex. B to Pl's Motion, Expert Report.

Plaintiffs do not appear to challenge Dr. Wagner's competency to testify that risks that did not appear on the IFUs were already commonly known to clinicians, but to the extent that their motion is construed as doing so, any such challenge should be denied. *Cf. In re: Ethicon*, 2016 WL 4582231, at *3 n. 2 (finding that Plaintiffs had not challenged this issue). Dr. Wagner will opine that the complications that Plaintiffs' experts claim should have been in the IFUs: (a) are risks that pelvic surgeons commonly knew, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device. *E.g.*, Ex. B to Pl's Motion,

[1] Dr. Wagner testified that he broadly considered all medical literature and did not rely on one article to the exclusion of others. Ex. B hereto, 3/13/17 Dep. 179:4-12. He also utilized the Oxford Pyramid of Evidence in assessing the weight to be accorded to evidence. Ex B to Pl's motion, Expert Report at 14-15.

Expert Report at 47-51. His opinions are based on his clinical experience as well as his thorough critique of scientific literature. *See, e.g., id.*; *see also Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12 (S.D. W.Va. Apr. 28, 2015).

Moreover, Dr. Wagner, as an experienced clinician and educator, is well qualified to testify about complications that are commonly known such that they need not be included in an IFU. The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) of Torts: Product Liability § 2 cmt. j (1998); Restatement (Second) of the Law of Torts § 402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device."

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Wagner is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how a clinician skilled in the art of pelvic floor surgery would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Wagner. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFUs failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

Finally, Plaintiffs suggest that the Court should exclude Dr. Wagner's warning opinions, because he supposedly only reviewed the 2015 version of the TVT IFU. *See* Doc. 3618 (citing Ex. E thereto, 3/13/17 Dep. 196:12-17). The citation, however, simply does not support Plaintiffs' assertion, and regardless, Plaintiffs' challenge otherwise lacks merit. For instance, Plaintiffs do not show that this has any bearing on Dr. Collins's overarching opinion that it was not necessary for the IFUs to include risks that were commonly known. To the extent that Plaintiffs take issue with Dr. Wagner's warning opinions, they may pursue those issues on cross-examination.

II. The Court should allow Dr. Wagner to provide certain design and scientific property opinions.

Despite Dr. Wagner's qualifications as a urogynecologist, Plaintiffs argue that he is not competent to provide opinions about the "design and the material properties of Ethicon's TVT device." (Doc. 3618, p. 3). The only opinions that Plaintiffs claim to fall within this category are opinions about "degradation, weight, porosity, and cut (laser or mechanical). *Id.* at 4. Once again, Plaintiffs' argument is vague and generic, and Plaintiffs do not cite to any portion of Dr. Wagner's report. For instance, in support of their argument that he "arbitrarily offers opinions regarding the design and the material properties of Ethicon's TVT device," Plaintiffs cite Dr. Wagner's entire report. *Id.* at 3 & n. 11. The Court should deny Plaintiffs' motion for lack of specificity and otherwise determine that Dr. Wagner is competent to render opinions that may touch upon design and material properties.

A. "Design" Opinions

Dr. Wagner does not purport to be an expert on the design process. As noted by Dr. Wagner, he is a design expert only from a clinical perspective based on his clinical experience

and review of the literature. *See* Ex. B hereto, 3/13/17 Dep. 148:16-150:4, 187:15-22. In rejecting a similar challenge to one of Ethicon's other urogynecologist experts, Dr. Michael Woods, the Court noted that Plaintiffs' motion is "plagued with confusion about what constitutes a design opinion," and found that "Dr. Woods has not expressed any opinions about the process of designing a product." *In re: Ethicon*, 2016 WL 4582231, at *3. As with that case, the Court should deny Plaintiffs' challenge as "moot." *Id.*

To extent that Plaintiffs have appropriately challenged Dr. Wagner's ability to opine that the PROLENE mesh in TVT is of the appropriate weight and porosity, Plaintiffs' challenge lacks merit. *See* Ex. B to Pl's motion, Expert Report at 34-35, 45-46. Dr. Wagner appropriately bases his opinion on his clinical experience and review of the medical literature. *Id.* Dr. Wagner is well-qualified to explain that the Okulu study cited by Plaintiffs' experts "provides no credible basis to conclude that [alternative] materials would be safer than the Prolene mesh in TVT." *Id.* at 46. If Plaintiffs' expert clinicians are allowed to reference this study, fairness dictates that Dr. Wagner be allowed to explain to the jury that this study is inapposite.

Dr. Wagner is also well qualified to testify that there is no increased risk of safety issues based on the manner by which the mesh is cut (whether by laser or machine). Dr. Wagner bases his opinions on his personal clinical experiences, as well as his review of the medical literature. *Id.* at 45-46; Ex. B hereto, 3/13/17 Dep. 131:20-133:13, 163:4-167:23. As noted by Dr. Wagner, "I have searched for literature that comparatively studies tapes with mechanical cut vs. laser cut mesh and have found none, much less one that concludes that a particular method of cutting has a bearing on the safety of the device." Ex. B to Pl's motion, Expert Report at 46.

B. "Properties" Opinions

Plaintiffs also vaguely argue that, because he is not a pathologist or a biomedical engineer, Dr. Wagner is not competent to testify about degradation and other unspecified issues touching upon mesh properties. The Court has consistently found similar challenges to be "without merit" and noted that the Defendants' urogynecologist experts' "extensive clinical and research experience qualifies [them] to opine on mesh's reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 45493666, at *3 (S.D.W. Va. Aug. 25, 2016); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4556807, at *4 (S.D.W. Va. Aug. 31, 2016).

Dr. Wagner's opinions about degradation are summarized on pages 33-38 of his report. Ex. B to Pl's motion. His opinions are not at the molecular level and the equivalent of the opinions of a biomedical engineer or polymer chemist, but instead, focused on clinical aspects of alleged degradation. *See Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *20 (S.D. W. Va. May 5, 2015) ("That he has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about 'what's happening at the molecular level'"). According to Dr. Wagner: "I've watched how [the PROLENE mesh in TVT has] performed not only in my patients, but also how it's performed through the vast years of medical literature and studies have been done on it." Ex. B hereto, 3/13/17 Dep. 184:23-185:14. He states, for instance, that, based on his extensive clinical experience, "I have never seen any evidence of degradation of polypropylene mesh." Ex. B to Pl's motion, Expert Report at 36. His review of the medical literature has bolstered his conclusion that mesh does not degrade and that, even if it did, it does not do so "in any way that manifests clinically for patients." *Id.* at 35.

In these MDLs, the Court has allowed urologists and gynecologists with similar qualifications as Dr. Wagner to testify about degradation and other issues touching upon properties. For instance, in *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *45 (S.D. W. Va. Apr. 28, 2016), the plaintiff argued that Dr. Michael Douso, a urogynecologist, was not qualified to testify about the physical properties of mesh and to offer opinions about degradation and similar topics because he was not a biomaterials or polymer science expert. In rejecting this challenge, the Court stated as follows:

> As to qualification, Dr. Douso is a practicing urogynecologist, and he is board-certified in obstetrics and gynecology. He has extensive experience with BSC's produces for treating SUI and POP, including use of the Prefyx and Uphold mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc.*, 878 F.2d at 799. I **FIND** that Dr. Douso's extensive experience qualified him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices.
>
> * * *
>
> The literature on which Dr. Douso relies includes multiple studies regarding polypropylene mesh devices and on the body's post-operative reaction to the mesh.
>
> The court has permitted physicians in related cases to offer similar opinions based on their clinical experience and review of the scientific literature. *See Tyree*, 54 F. Supp. 3d at 585 (finding an expert's "clinical experience and review of the scientific literature are sufficiently reliable bases in forming this particular opinion"). Accordingly, I **FIND** that Dr. Douso's extensive clinical experience

> and literature review provide a sufficient reliable basis for his opinions. The plaintiff's motion on this point is **DENIED**.

2016 WL 1718836, at *46 (other citations omitted); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); *id.* at *33 (allowing testimony of defense expert Patrick Culligan, M.D.); *Huskey*, 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 550, 585 (S.D.W. Va. 2014) (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.); *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], pp. 6–9.

Under Plaintiffs' own theory, if Dr. Wagner is not competent to testify about these particular issues touching upon design and mesh properties, then none of Plaintiffs' clinician experts in these cases are competent to opine on these issues.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that the Court deny Plaintiffs' motion to exclude Dr. Collins's opinions.

Respectfully submitted,

/s/Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS

CERTIFICATE OF SERVICE

I hereby certify that on this day, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com